

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

EAGLE PHARMACEUTICALS, INC.,

Plaintiff,

v.

SLAYBACK PHARMA LLC,

Defendant.

C.A. No.

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Eagle Pharmaceuticals, Inc. (“Eagle”), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, to enjoin, and obtain damages resulting from, Slayback Pharma LLC’s (“Slayback”) unauthorized importation into the United States, and use, sale, and/or offer for sale of products in the United States, that infringe at least one claim of Eagle’s United States Patent No. 12,138,248 (the “’248 patent” or the “Patent-in-Suit”).

2. Slayback submitted New Drug Application (“NDA”) No. 212209 to the United States Food and Drug Administration (“FDA”), seeking approval to manufacture and sell a product that relies on data from bioavailability and/or bioequivalence studies contained in the Approved Labeling for Eagle’s BELRAPZO®, 100 mg/4 mL (25 mg/mL) Bendamustine Hydrochloride Injection product, prior to the expiration of the Patent-in-Suit.

3. On information and belief, the FDA granted approval of Slayback’s NDA No. 212209 on December 7, 2022. Following said approval, Slayback began to import into the United States, and/or use, sell, and/or offer to sell in the United States, its NDA Product, VIVIMUSTA®

(bendamustine hydrochloride injection) 100 mg/4 mL (25 mg/mL), along with the Approved Labeling for the same.

PARTIES

4. Plaintiff Eagle is a corporation organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

5. On information and belief, Defendant Slayback is a company organized and existing under the laws of Delaware, with its principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08540.

6. The Approved Labeling for VIVIMUSTA® recites that it is “Manufactured at: Latina Pharma S.p.A. 04013 Sermoneta (LT), Italy” and “Manufactured for: Slayback Pharma LLC Princeton, NJ 08540.” Approved Labeling for VIVIMUSTA®, (the “Approved Labeling”), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212209s005lbl.pdf (last visited January 17, 2025) at 22. On information and belief, Slayback directly or indirectly markets, sells, and distributes VIVIMUSTA® throughout the United States, including in Delaware.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Slayback is incorporated in Delaware and therefore resides there for purposes of venue.

9. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Slayback.

10. This Court has personal jurisdiction over Slayback because, upon information and belief, Slayback is a company organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware, at 1209 Orange Street, Wilmington, Delaware, 19801. This Court has personal jurisdiction over Slayback for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

11. In addition, this Court has personal jurisdiction over Slayback because, on information and belief, Slayback has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

12. Further, this Court also has personal jurisdiction over Slayback because, among other things, on information and belief: (1) Slayback filed NDA No. 212209 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in NDA No. 212209 in the United States, including in Delaware; and (2) since NDA No. 212209 was approved, the product described in NDA No. 212209, VIVIMUSTA®, has been and continues to be imported, marketed, distributed, offered for sale, and/or sold in the United States, including in Delaware.

13. The Court also has personal jurisdiction over Slayback because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has harmed and injured Eagle, which is a Delaware corporation.

14. Slayback has previously consented to jurisdiction in Delaware in many prior cases arising out of the filing of its drug applications, including the application for the product at issue in this litigation, and it has asserted counterclaims in such cases. *See, e.g., Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 17-1154-CFC, D.I. 11 (D. Del. Sep. 29, 2017); *Teva*

Pharma. Int'l GmbH, Cephalon, Inc. & Eagle Pharma., Inc. v. Slayback Pharma LLC, No. 18-117-CFC, D.I. 9 (D. Del. Feb. 12, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-1459-CFC, D.I. 9 (D. Del. Oct. 10, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-1953-CFC, D.I. 12 (D. Del. Jan. 3, 2019); *Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 24-65-JLH, D.I. 14 (D. Del. Apr. 1, 2024).

15. For at least the above reasons, it would not be unfair or unreasonable for Slayback to litigate this action in this District, and there is personal jurisdiction over Slayback for purposes of this action.

BACKGROUND

16. BELRAPZO®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

17. Eagle is the holder of NDA No. 205580 for BELRAPZO®, which has been approved by the FDA.

18. The '248 patent, entitled "Formulations of Bendamustine" (Exhibit A hereto), was duly and legally issued on November 12, 2024. Eagle is the owner and assignee of the '248 patent.

19. Claim 1 of the '248 patent recites:

A sterile container containing a liquid bendamustine-containing composition comprising bendamustine, or a pharmaceutically acceptable salt thereof, wherein the bendamustine concentration in the composition is about 25 mg/mL;

a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol; and

a stabilizing amount of an antioxidant,

wherein the total impurities resulting from the degradation of the bendamustine is less than about 5% peak area response, as determined by HPLC at a wavelength of 223 nm after at least about 15 months at a temperature of about 5 °C to about 25 °C.

20. BELRAPZO® is a product that falls within the ambit of at least claim 1 of the '248 patent.

21. BENDEKA® is a drug product marketed by Teva Pharmaceuticals ("Teva") under a license from Eagle to Teva. BENDEKA® likewise is a drug product that falls within the ambit of at least claim 1 of the '248 patent.

INFRINGEMENT BY SLAYBACK

22. On information and belief, Slayback's NDA Product, marketed and sold as VIVIMUSTA®, received final approval from the FDA on December 7, 2022. *See* Drugs@FDA, Vivimusta, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212209> (last visited January 17, 2025).

23. On information and belief, since the approval of VIVIMUSTA®, Slayback has been importing VIVIMUSTA® into the United States, using VIVIMUSTA® in the United States, offering VIVIMUSTA® for sale in the United States, and selling VIVIMUSTA® in the United States. VIVIMUSTA® is prominently listed as a product for sale by Slayback on the Slayback website. *See* <https://vivimusta.com/> (last visited January 17, 2025).

24. Upon information and belief, VIVIMUSTA® relies on data from bioavailability and/or bioequivalence studies contained in the Approved Labeling for BELRAPZO®. BELRAPZO® is approved for a 24-month shelf life. The Approved Labeling for VIVIMUSTA® does not identify any difference in stability between VIVIMUSTA® and BELRAPZO® and, upon information and belief, VIVIMUSTA® has the same or substantially similar stability as BELRAPZO® and/or as recited in the claims of the Patent-in-Suit.

25. Publicly-available materials from the FDA’s review of Slayback’s NDA No. 212209 indicate that “in the September 16, 2019 CRL, [Slayback] provided updated stability data for the finished product in support of the proposed 24-month expiry. Based on the information provided, Slayback Pharma LLC. proposed and the FDA accepts the expiration dating period of **24 months** for the drug product when stored at [sic] between 2–8 °C.” Product Quality Review(s), Application No. 212209Orig1s000, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/212209Orig1s000ChemR.pdf (last visited January 17, 2025) (the “Product Quality Review”) at p. 37. Thus, on information and belief, VIVIMUSTA®, as sold, used, or offered for sale in the United States, satisfies the stability limitations set forth in the claims of the Patent-in-Suit.

26. The Approved Labeling for VIVIMUSTA® states that the active ingredient is bendamustine hydrochloride. *See* Approved Labeling at 1; *see also Eagle Pharm., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

27. The Approved Labeling for VIVIMUSTA® states that the dosage strength is 25 mg/mL. *See id.*

28. The Approved Labeling for VIVIMUSTA® states that it contains polyethylene glycol (“PEG”), which is described and claimed as a pharmaceutically acceptable fluid in the Patent-in-Suit. *See id.* at 15. The Approved Labeling for VIVIMUSTA® further states that it contains “absolute alcohol,” which is a known, commercially available grade of ethanol, which is likewise described and claimed as a pharmaceutically acceptable fluid in the Patent-in-Suit. *See id.* Thus, Slayback’s VIVIMUSTA® contains “a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally . . . ethanol,” consistent with claim 1 of each of the Patent-in-Suit.

29. The Approved Labeling for VIVIMUSTA® also recites that “[e]ach milliliter contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) of absolute alcohol, and q.s. to 1 mL polyethylene glycol 400.” *Id.* at 15. The Approved Labeling then states: “Sodium hydroxide is used to adjust [the] pH of polyethylene glycol 400.” *Id.* Sodium hydroxide is not a pharmaceutically acceptable fluid as that term is used in the specification of the ’248 patent, nor is it a component of the pharmaceutically acceptable fluid in VIVIMUSTA®. Thus, it is not pertinent to the “pharmaceutically acceptable fluid” limitation of claim 1 of each of the Patent-in-Suit.

30. Indeed, in referring to the use of sodium hydroxide, the Approved Labeling does not describe sodium hydroxide as a component of VIVIMUSTA®, but rather notes that “sodium hydroxide is used to adjust [the] pH *of polyethylene glycol 400*” used to manufacture VIVIMUSTA®. *Id.* at 15. Thus, that fluid remains “*polyethylene glycol 400*” and is not taken outside the confines of being a “pharmaceutically acceptable fluid” by any use of sodium hydroxide during its preparation.

31. The Approved Labeling notes that VIVIMUSTA® is “Manufactured at: Latina Pharma S.p.A.” in “Sermoneta (LT), Italy.” *Id.* at 22. In certain instances, on information and belief, Slayback’s Italian manufacturer uses sodium hydroxide in batches of PEG. In those instances, any addition of sodium hydroxide to the PEG during manufacturing in Italy is for the purposes of ensuring that VIVIMUSTA® has a pharmaceutically acceptable fluid as part of its liquid bendamustine-containing formulation at the time of importation, offer for sale, use, and/or sale of same in the United States.

32. Publicly-available materials from the FDA’s review of Slayback’s NDA No. 212209 indicate that sodium hydroxide is only used in a “quantity sufficient” to “adjust [the] pH of polyethylene glycol 400.” Product Quality Review at p. 6, 67.

33. The Approved Labeling similarly does not list a specific amount of sodium hydroxide or indicate that it is necessary in all instances. Rather, the Approved Labeling for VIVIMUSTA® recites that “[e]ach milliliter contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) of absolute alcohol, and q.s. to 1 mL polyethylene glycol 400.” *Id.* at 15. Therefore, on information and belief, while the Approved Labeling states that “[s]odium hydroxide is used to adjust [the] pH of polyethylene glycol 400” in VIVIMUSTA® (Approved Labeling at 15), sodium hydroxide is not used for each batch of the PEG used in the manufacture of VIVIMUSTA®.

34. Even in an instance where sodium hydroxide is used to adjust the pH of batches of PEG used to manufacture VIVIMUSTA®, on information and belief, sodium hydroxide is not a component of the product that is imported into the United States, sold and/or offered for sale in the United States, and/or used in the United States. Thus, the Approved Labeling for VIVIMUSTA® recites that “[e]ach milliliter contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) of absolute alcohol, and q.s. to 1 mL polyethylene glycol 400.” *Id.* at 15. As explained on Slayback’s Approved Labeling, sodium hydroxide is used as a pH adjuster and, on information and belief, is consumed by such use and/or is otherwise not a component of VIVIMUSTA®.

35. Additionally, the use of sodium hydroxide is well known to those of skill in the art to adjust the pH of both pharmaceutical formulations generally, and of PEG specifically. Sodium Hydroxide, National Library of Medicine, <https://pubchem.ncbi.nlm.nih.gov/compound/Sodium->

Hydroxide, (last visited January 17, 2025). Thus, even if Slayback’s Italian manufacturer uses sodium hydroxide to adjust the pH of PEG in the manufacturing process, a person of ordinary skill in the art would not consider any such use to take VIVIMUSTA® outside the scope of the claim element “a pharmaceutically acceptable fluid consisting of polyethylene glycol and optionally one or more of propylene glycol, ethanol, benzyl alcohol and glycofurol.” *See, e.g.*, ’248 patent at claim 1. Further, by time of importation, offer for sale, use, and/or sale, VIVIMUSTA® has a pharmaceutically acceptable fluid as part of its liquid bendamustine-containing formulation given that Slayback promotes that it is pharmaceutically acceptable for administration to humans. “VIVIMUSTA is an alkylating drug indicated for the treatment of adult patients . . .” <https://vivimusta.com/> (last visited January 17, 2025).

36. The Approved Labeling for VIVIMUSTA® also recites that “[e]ach milliliter contains 25 mg of bendamustine hydrochloride [and] . . . 5 mg of monothioglycerol.” Approved Labeling at 15. The shared specification for the Patent-in-Suit indicates that monothioglycerol is an antioxidant and that 5 mg/mL is a stabilizing amount of an antioxidant.

37. Upon information and belief, VIVIMUSTA® has less than about 5% peak area response of total impurities resulting from the degradation of the bendamustine, as determined by HPLC at a wavelength of 223 nm after at least 15 months at a temperature of from about 5 °C to about 25 °C. Further, Slayback has conceded that VIVIMUSTA® meets an identical limitation in U.S. Patent No. 9,572,796, which is related to the Patent-in-Suit and shares a specification with them. *Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1173 (Fed. Cir. 2020).

38. The Approved Labeling for VIVIMUSTA® encourages, recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia. *See* Approved Labeling.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 12,138,248

39. Eagle incorporates each of the preceding paragraphs as if fully set forth herein.

40. As set forth herein, Slayback has offered VIVIMUSTA® for sale in the United States, sold VIVIMUSTA® in the United States, used VIVIMUSTA® in the United States, and/or imported VIVIMUSTA® into the United States.

41. Upon information and belief, the importation, manufacture, sale, offer for sale, and/or use of VIVIMUSTA® in conjunction with its Approved Labeling infringes one or more claims, including at least claim 1, of the '248 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Slayback induces or contributes to the inducement of the infringement of one or more claims, including at least claim 1, of the '214 patent under 35 U.S.C. § 271(b) and/or (c).

42. As reflected in its Approved Labeling, each milliliter of VIVIMUSTA® “contains 25 mg of bendamustine hydrochloride equivalent to 22.7 mg of bendamustine, 5 mg of monothioglycerol, 39.45 mg (5% v/v) absolute alcohol, and q.s. to 1 mL polyethylene glycol 400.” Approved Labeling at 15. That Approved Labeling further indicates that VIVIMUSTA® is marketed in a 100 mg/4 mL vial. *Id.* at 20.

43. The foregoing actions by Slayback constitute infringement of the '248 patent, active inducement of infringement of the '248 patent, and contribution to the infringement by others of the '248 patent.

44. Slayback's infringement and/or inducement is willful. Upon information and belief, Slayback is aware of the '248 patent at least because Slayback is aware of Eagle's patent portfolio and has previously been involved in litigation concerning other patents related to the '248 patent. *See, e.g., Eagle Pharm. Inc. v. Slayback Pharma LLC*, No. 21-1256-CFC, D.I. 9 (D. Del. Sept. 22, 2021). Further, Slayback has been aware of the '248 patent and their related infringement at least since Eagle sent a letter to Slayback dated November 12, 2024, informing Slayback that the '248 patent had issued and that Slayback was infringing that patent through the importation, sale, offer for sale, and/or use of VIVIMUSTA® in conjunction with its Approved Labeling. Moreover, upon information and belief, Slayback has regularly monitored Eagle's patent filings and developments in the '248 patent family.

45. Upon information and belief, Slayback has acted with full knowledge of the '248 patent and/or the application leading to the '248 patent, Application No. 18/646,171, and without a reasonable basis for believing that it would not be liable for infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent.

46. Unless Slayback is enjoined from infringing the '248 patent, actively inducing infringement of the '248 patent, and contributing to the infringement by others of the '248 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

47. Eagle has suffered monetary damages, including but not limited to lost profits, as a result of Slayback's infringement of the '248 patent.

JURY DEMAND

48. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Eagle hereby demands a trial by jury on all issues triable as such.

PRAYER FOR RELIEF

WHEREFORE, Eagle requests the following relief:

(a) A judgment that Slayback has infringed, and induced and contributed to infringement of the Patent-in-Suit;

(b) A permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 283 enjoining Slayback, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Slayback's NDA Product, VIVIMUSTA®, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patent-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the Patent-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Slayback's NDA Product, VIVIMUSTA®, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patent-in-Suit, prior to the expiration date of the Patent-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patent-in-Suit;

(d) An award of Eagle's damages or other monetary relief to compensate Eagle for Slayback's past infringement and any continuing or future infringement of the Patent-in-Suit up until the date such judgement is entered, including pre- and post-judgement interest, costs, and disbursements as justified pursuant to 35 U.S.C. § 284;

(e) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

- (f) An award of Eagle's costs and expenses in this action; and
- (g) Such further and other relief as this Court may deem just and proper.

Dated: January 17, 2025

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